Amendment Dated: April 29, 2008

Reply to Office Action Mailed December 5, 2007

REMARKS/ARGUMENTS

Claims 1, 2, 4, 6 and 8 are pending in the instant application. Claims 11 through 15 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 3, 5, 7, 9 and 10 are also withdrawn from further consideration as being drawn to a nonelected species. Claims 1 and 2 have been amended, support for which may be found at page 10, line 15, through page 11, line 16, and elsewhere within applicant's specification, as originally filed. Claim 8 has been amended to now depend from claim 3 and, since it now depends solely from a withdrawn claim, is also withdrawn.

The Examiner has objected to claim 8 due to the presence of informalities. The Examiner has rejected claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by Foerster, U.S. Publication No. 2002/0029066 A1. The Examiner has rejected claims 1, 4, 6 and 8 under 35 U.S.C. 102(b) as being anticipated by Burton, U.S. Patent No. 4,159,720. The Examiner has rejected claim 2 under 35 U.S.C. 103(a) as being unpatentable over Foerster, U.S. Publication No. 2002/0029066 A1. The objection to applicant's claim 8 and the rejection of applicant's claims 1, 2, 4, 6 and 8 are respectfully traversed. Reconsideration and favorable action is respectfully solicited in view of the following.

The Examiner has objected to claim 8 due to the presence of informalities.

The Examiner has stated that:

Claim 8 is objected to because of the following informalities: Claim 8 recites "the coated fiber tow" which does not have proper antecedent basis. Appropriate correction is required.

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In response thereto, the applicant has amended claim 8 to address the issue raised by the Examiner. Since claim 8 now depends solely from a withdrawn claim, it is also withdrawn. In view thereof, it is respectfully requested that the grounds for objection to claim 8 be removed.

The Examiner has rejected claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by Foerster, U.S. Publication No. 2002/0029066 A1. The Examiner is of the view that:

With regard to claim 1, Foerster discloses a hollow braided suture having proximal and distal ends (see entire document, specifically abstract). As shown in Figures 11 and 12, the suture material is threaded back upon itself through the inner lumen. Therefore, the inner suture material forms a passageway that is coaxial with the outer braided suture material. Additionally, the distal end of the inner passageway is disposed between the proximal and distal ends of the outer braided suture material.

With regard to claim 4, since the inner suture material comprises a hollow suture, it clearly overlaps the instantly claimed lumen of a tube.

Contrary to the position adopted by the Examiner, Foerster, U.S. Publication No. 2002/0029066 A1, proposes single-tailed suturing method and apparatus. In use, it is proposed that a suture loop be formed in a hollow braided suture by feeding one end of a length of suture through a part in the braid of the suture and into the inner lumen formed by the hollow braid. The braided configuration of the suture allows it to be expanded in diameter by pushing and reduced in diameter by pulling. The end of the suture is passed continuously through the inner lumen forming a loop of suture with a single tail. The loop may be tightened by pulling on the first end of the suture while pushing on said outer hollow braid. The loop may be locked by extending or pulling on said outer hollow braid to reduce its diameter and lock it down around said first end of the suture.

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A careful review of the Foerster reference reveals that nowhere is an active suture that includes a braided suture having proximal and distal ends and an outer diameter, said braided suture having a plurality of interstices along at least a portion of its length; and at least one passageway coaxial with at least a portion of the braided suture, and having proximal and distal ends and a diameter that is less than the outer diameter of the braided suture and having one or more openings therein so that said at least one passageway conducts fluid to said plurality of interstices of said braided suture; wherein the distal end of the at least one passageway is disposed between the proximal and distal ends of the braided suture, fairly taught within its four comers. [Emphasis added]. Likewise, nowhere is an active suture that includes a braided suture having an outer diameter_said braided suture having a plurality of interstices along at least a portion of its length; and a tube coaxial with at least a portion of the braided suture, having an outer diameter that is less than the outer diameter of the braided suture and an inner diameter, and having one or more openings therein so that said at least one passageway conducts fluid to said plurality of interstices of said braided suture; wherein the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7 fairly taught. [Emphasis added]. Moreover, there is no description capable of enabling a person of ordinary skill to make the invention without undue experimentation. Since Foerster fails to describe each and every limitation of the present claims, Foerster cannot serve to anticipate applicant's claimed invention.

As stated in MPEP § 2131, in order to constitute anticipation under the law, a patent or publication must contain within its four corners a sufficient description to enable the person of ordinary skill to make the invention without undue experimentation. All material elements of a claim must be found in one prior art source, a mere suggestion is not enough and essential elements are not to be read into a reference. Foerster clearly fails to teach each and every element of

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applicant's invention, as presently claimed. Nowhere does Foerster disclose an active suture that includes a passageway for conducting fluid to the plurality of interstices of the braided suture. Accordingly, it is respectfully requested that the Examiner's rejection of claims 1 and 4 under 35 U.S.C. 102(b) as being anticipated by Foerster, U.S. Publication No. 2002/0029066 A1, be withdrawn.

The Examiner has rejected claims 1, 4, 6 and 8 under 35 U.S.C. 102(b) as being anticipated by Burton, U.S. Patent No. 4,159,720. The Examiner is of the view that:

With regard to claim 1, Burton discloses a braided suture having proximal and distal ends (see entire document). As shown in Figure 14, the suture comprises a hollow inner passageway coaxial with the braided suture (column 4, lines 46-49). A prescribed fluid runs through this passageway to facilitate healing of the damaged tissue (column 2, lines 13-18). However, Burton does not specifically disclose wherein the distal end of the passageway is disposed between the proximal and distal ends of the braided suture. If this were not the case, then the distal end of the passageway would be open, allowing the fluid to directly flow into the passageway. However, Burton teaches that the ends of the suture absorb the fluid (column 5, lines 6-8). Therefore, since the fluid is absorbed, suture material must be present at the distal end to take in the fluid.

With regard to claim 4, it is the examiner's position that the inner passageway is a lumen of a tube.

With regard to claim 6, holes (102) connect the inner lumen to the outer surface of the suture tube (column 4, lines 46-49; Figure 14).

With regard to claim 8, the proximal end of the suture is connected to a needle (60) or to an intravenous delivery system (10) (Figures 6 and 10; column 3, lines 11-25; column 5, lines 38-54). Therefore a connector is present on the proximal end of the passageway to provide the connection between the passageway and needle or delivery system.

Burton, U.S. Patent No. 4,159,720, proposes a means for delivering a prescribed liquid medicine or other fluid to a subcutaneous tissue. The device includes a reservoir on the outside of the body for holding a supply of the

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prescribed liquid, the reservoir being adhesively attached to the skin near the tissue to be treated. The reservoir feeds the liquid to absorbent or capillary wicks adapted to pass through the skin to be installed in the subcutaneous tissue to which the fluid is to be fed. The wicks may be provided in several forms such as twisted or braided suture material, the ends of which, in some instances, may be encased in plastic. The wicks, in whatever form, are guided from the outside into their installed positions in the subcutaneous tissue with conventional cutting or tapered surgical needles, and in the modification making use of a plastic casing, a slightly modified needle is used to install the wick cover.

Applicant wishes to point out that Burton merely teaches that the "wick," not a "braided suture," can be a hollow monofilament. As such, Burton proposes a braided suture, and a connector, or, alternatively, a hollow monofilament, and a connector. Nowhere does Burton describe the use of both the braided suture and the hollow monofilament in the same assembly.

A careful review of the Burton reference reveals that nowhere is an active suture that includes a braided suture having proximal and distal ends and an outer diameter, said braided suture having a plurality of interstices along at least a portion of its length; and at least one passageway coaxial with at least a portion of the braided suture, and having proximal and distal ends and a diameter that is less than the outer diameter of the braided suture and having one or more openings therein so that said at least one passageway conducts fluid to said plurality of interstices of said braided suture; wherein the distal end of the at least one passageway is disposed between the proximal and distal ends of the braided suture, fairly taught within its four comers. [Emphasis added]. Likewise, nowhere is an active suture that includes a braided suture having an outer diameter said braided suture having a plurality of interstices along at least a portion of its length; and a tube coaxial with at least a portion of the braided suture, having

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an outer diameter that is less than the outer diameter of the braided suture and an inner diameter, and having one or more openings therein so that said at least one passageway conducts fluid to said plurality of interstices of said braided suture; wherein the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7 fairly taught. [Emphasis added]. Moreover, there is no description capable of enabling a person of ordinary skill to make the invention without undue experimentation. Since Burton fails to describe each and every limitation of the present claims, Burton cannot serve to anticipate applicant's claimed invention.

As stated in MPEP § 2131, in order to constitute anticipation under the law, a patent or publication must contain within its four comers a sufficient description to enable the person of ordinary skill to make the invention without undue experimentation. All material elements of a claim must be found in one prior art source, a mere suggestion is not enough and essential elements are not to be read into a reference. Burton clearly fails to teach each and every element of applicant's invention, as presently claimed. Nowhere does Burton disclose an active suture that includes a tube having an internal passageway for conducting fluid to the plurality of interstices of the braided suture. Accordingly, it is respectfully requested that the Examiner's rejection of claims 1, 4, 6 and 8 under 35 U.S.C. 102(b) as being anticipated by Burton, U.S. Patent No. 4,159,720, be withdrawn.

The Examiner has rejected claim 2 under 35 U.S.C. 103(a) as being unpatentable over Foerster, U.S. Publication No. 2002/0029066 A1. The Examiner is of the view that:

Foerster discloses a hollow braided suture having proximal and distal ends (see entire document, specifically abstract). As shown in Figures 11 and 12, the suture material is threaded back upon itself through the inner lumen. Therefore, the inner suture material forms a tube that is coaxial with the outer braided suture material. Since the tube is threaded through the suture

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material as shown in Figure 10, the suture material inherently has at least one opening through which the tube is threaded (100801). However, Foerster does not specifically disclose the ratio of the outer diameter of the tube to the inner diameter of the tube. However, it would have been obvious to one of ordinary skill at the time of the invention for Foerster to also comprise a tube diameter ratio of greater than 17.7 since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 105 USPQ 233 (CCPA 1955)).

As indicated above, Foerster, U.S. Publication No. 2002/0029066 A1, proposes single-tailed suturing method and apparatus. In use, it is proposed that a suture loop be formed in a hollow braided suture by feeding one end of a length of suture through a part in the braid of the suture and into the inner lumen formed by the hollow braid. The braided configuration of the suture allows it to be expanded in diameter by pushing and reduced in diameter by pulling. The end of the suture is passed continuously through the inner lumen forming a loop of suture with a single tail. The loop may be tightened by pulling on the first end of the suture while pushing on said outer hollow braid. The loop may be locked by extending or pulling on said outer hollow braid to reduce its diameter and lock it down around said first end of the suture

A careful review of the Foerster reference reveals that nowhere is an active suture that includes a braided suture having an outer diameter <u>said braided suture having a plurality of interstices along at least a portion of its length;</u> and a tube coaxial with at least a portion of the braided suture, having an outer diameter that is less than the outer diameter of the braided suture and an inner diameter, and having one or more openings therein <u>so that said at least one passageway conducts fluid to said plurality of interstices of said braided suture;</u> wherein the ratio of the outer diameter of the tube to the inner diameter of the tube is greater than 1.7 fairly taught or suggested. [Emphasis added].

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It is respectfully submitted that, as the Federal Circuit noted in In re Gordon, at 221 USPQ 1127, 733 F.2d 902, "the mere fact that the reference could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." It is respectfully submitted that the lack of technical motivation for making the modifications necessary to arrive at applicant's claimed invention is evidence that the suggestion for the modification could not have come from the reference itself. In view thereof, the applicant respectfully requests that the rejection of claim 2 under 35 U.S.C. 103(a) as being unpatentable over Foerster, U.S. Publication No. 2002/0029066 A1. be removed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478(14619).

It is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully solicited.

Respectfully submitted,

Date: April 29, 2008

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Patent Assignment Abstract of Title

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Title: Active suture for the delivery of therapeutic fluids

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Assignor: CICHOCKI, JR., FRANK R. Exec Dt: 12/03/2003

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